Serial Number: 10/567,876 Filing Date: February 8, 2006

Title: Metalloproteinase Gene Polymorphism in COPD

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on June 2, 2008, and the references cited therewith. Claims 1 and 19 are amended.

§112 Rejection of the Claims

Claims 1-9 were rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding item 5 of the office action dated June 2, 2008, the Examiner states that references to Lose et al. and Ganter et al. teach that asthma is not associated with a polymorphism in MMP-9 gene at Arg279Gln and that the reference of Saitoh teaches a polymorphism of MMP-14 is associated with COPD in varying ethnic groups. Further, the Examiner states that Nakashima et al. teach that SNP10 in MMP-9 is not associated with childhood asthma in a Japanese population.

Claim 1 as been amended to provide the method of determining susceptibility of hispanic and non-hispanic white men to a chronic obstructive pulmonary disorder (COPD) excluding asthma and chronic bronchitis comprising the step of determining the presence of an exon 6 codon 279 Gln/Arg single nucleotide polymorphism within the matrix metalloproteinase-9 (MMP-9) locus in a biological sample obtained from the individual, wherein the 279 arginine polymorphism indicates susceptibility to chronic obstructive pulmonary disorder. The exclusion of asthma and chronic bronchitis from COPD finds support in the specification at page 21 lines 25-30. The support in the specification for a method determining susceptibility of Hispanic and nonhispanic whites to COPD is found at page 30 lines 1-12. Specifically, the specification teaches that there is a higher prevalence of the 279Arg homozygote genotype and the heterozygote genotype in participants with COPD compared to non-COPD participants. The trend is predicted to be seen in a Hispanic population when the pool of Hispanic participants with COPD increases to the size seen in the study for non-hispanic white participants exhibiting the trend.

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The reference to Saitoh is directed to MMP-14 which is different than MMP-9. Applicant

fails to understand the relevance of this reference as the behavior of MMP-14 in varying

populations is not relevant to Applicant's invention.

There is no undue experimentation as suggested by the Examiner as the procedure is well

established and easily reproduced. The claims as amended do not require a large quantity of

experimentation to practice as there is sufficient teaching to guide one skilled in the art to

practice the invention.

Therefore the specification provides sufficient guidance to enable the claims as written to

be practiced without undue experimentation and therefore the claims 1-9 as amended satisfy 35

USC §112 first paragraph and should be allowed.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and

notification to that effect is earnestly requested. The Examiner is invited to telephone

Applicant's attorney (505-998-6134) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account

No. 13-4213

Respectfully submitted,

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